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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/470,667	12/22/99	ASAKURA	A 13735 (109700 BT
		HM12/0529	EXAMINER
			WALICKA, M
		ART UNIT	PAPER NUMBER
		1652	10
		DATE MAILED:	05/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/470,667	ASAKURA ET AL.
	Examiner Malgorzata A. Walicka	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_ is/are objected to.

8) Claims 1-28 are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.

18) Interview Summary (PTO-413) Paper No(s). \_\_\_\_.

19) Notice of Informal Patent Application (PTO-152)

20) Other: \_\_\_\_\_

Examiner acknowledges this continuing application filed under rule 1.53(b) on December 22, 1999. The preliminary amendment was entered as requested. Claims 1-28 are pending in the application and considered in this office action.

### **RESTRICTION/ELECTION**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3 and 9 drawn to an enzyme comprising a recombinant polypeptide having alcohol and aldehyde dehydrogenase activity classified in class 435, subclass 190.
- II. Claims 4-8, and 10-16, drawn to DNA encoding said enzyme, expression vectors, recombinant host, and recombinant production of the enzyme, classified in class 536, subclass 23.2, 320.1 and 252.3.
- III. Claims and 17 and 18, drawn to a process for producing aldehyde by the recombinant organism in a fermentor, classified in class 435, subclass 148.
- IV. Claim 19, drawn to a process for producing carboxylic acid by the recombinant microorganism in a fermentor, classified in class 435, subclass 136.
- V. Claim 20 and 21, drawn to a process for producing of aldehyde by the recombinant enzyme, classified in class 435, subclass 148.
- VI. Claim 23-24, drawn to a process for producing a 2-keto-L-gulonic acid by the recombinant organism grown on L-sorbose, classified in class 435, subclass 138.
- VII. Claim 22 and 25, drawn to a process for producing 2-keto-L-gulonic acid by the recombinant enzyme, classified in class 435, subclass 138.
- VIII. Claim 26 and 27, drawn to a process for the production of L-ascorbic acid from 2-keto-L-gulonic acid using the recombinant organism classified in class 435, subclass 41.
- IX. Claim 28, drawn to a process for the production of L-ascorbic acid from 2-keto-L-gulonic acid using the recombinant enzyme, classified in class 435, subclass 41.

The inventions are distinct, each from the other because:

Inventions of group I and II comprise different chemical entities, protein and DNA. The groups require separate search in the patent literature and publications. Inventions of Group I and II are also related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product, the recombinant enzyme, may be produced by chemical synthesis. Therefore, inventions of group I and II are different.

Inventions I and III, IV, VI, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are the recombinant enzyme of Group I and production of chemicals by the recombinant organisms in a fermentor claimed by Group III, IV, VI and VIII. Inventions I and III, IV, VI and VIII have different modes of operation and functions and are not capable of use together. Thus, they are distinct.

Inventions of group I and V, VII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The process for using the product can be practiced with another product. In the instant case aldehydes, ketones and carboxylic acids may be synthesized using a catalizator distinct from said recombinant enzyme.

Inventions II and III-IX are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claims will be examined along with the elected invention (MPEP § 806.05(i)).

Inventions III-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions III-IX relate to different method of production of different chemicals therefore they are not disclosed as capable of use together.

Inventions I-IX are distinct for the reasons given above and have acquired a separate status in the art. Because of their recognized divergent subject matter and/or different classification, restriction for examination purposes as indicated is proper.

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This application contains claims directed to the following patentably distinct species of the claimed invention: recombinant polypeptide containing an amino acid sequence selected from the group consisting of SEQ ID NOS:5-8 and DNA molecules of SEQ ID NOS:1-4 encoding these polypeptides.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 4, 6, 7, 8 and 25 are generic.

Applicants' attention is drawn to the fact that election of a polypeptide involves election of the appropriate expression vector. Currently, claim 8 recites 15 expression vectors.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claim 1 links inventions I and V. Claim 10 links inventions II, III, IV, VI, and VIII. Claim 25 links inventions VII and VIII and IX. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s) 1, 10 and 25. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.  
Art Unit 1652  
Assistant Patent Examiner



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